GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3571
ANSWERED ON:22.12.2004
NEW DRUG APPLICATIONS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of the new Drug applications received by the DCGI during the years 2003 & 2004;

(b) the names of the Drugs and the companies approved during the year 2004 along with the dates of receipt of applications and approval; and

(c) the new FDC combinations permitted for marketing during the year 2004?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) During the year 2003 & 2004 (upto 17.12.2004) the office of DCGI has received 1057 and 1136 New Drug applications respectively of various categories of New Drugs, which includes investigational New Drugs, New Drug molecules, subsequent approval, new fixed dose combination, New dosage form, New indication etc.

(b) The evaluation of new drug applications is a complex process as per Schedule - Y under Drugs & Cosmetics Rules and varies according to the nature of molecule/drug, published data and information furnished by the applicants. Therefore, depending upon the nature of the application, it may take on an average 3 to 5 years for an applicant to complete all phase of trials required for approval of investigational New Drug (i.e. a drug molecule not tested on human being anywhere in the world); about 1-3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial, and about 2-3 months for subsequent applications for already approved drugs. This is however, subject to submission of all required data as per provisions of Schedule - Y of Drug & Cosmetics Rules and opinion from experts.

Names of the New Drug molecules approved during the year 2004 alongwith the name of companies, date of receipt of application and approval is annexed herewith (annexure-1).

(c) The new fixed dose combination (FDC) permitted for marketing during the year 2004 is annexed herewith (annexure-2).

ANNEXURE - I

NEW DRUGS (FIRST TIME APPROVAL) APPROVED DURING CURRENT YEAR, 2004 ALONGWITH NAME OF COMPANIES & DATE OF RECEIPT AND APPROVAL

Sl. No.	Name of Drugs	Name of Companies	Date of receipt	Date of approval
1	Dutasteride	M/s. Dr. Reddy`s Lab	26.09.2002	16.02.2004
2	Gefitinib	M/s. Astrazeneca	02.01.2004	17.02.2004
3	Imidapril	M/s. Elder Pharma	03.04.2001	23.02.2004
4	Adefovir	M/s. Cipla	16.04.2003	04.03.2004
5	Etoricoxib	M/s. Cadila Healthcare, Glenmark, Hetero	Cadila -24.04.2003 Glenmark 30.05.2003 Hetero 13.05.2003	05.03.2004
6	Diacerin	M/s. Elder Pharma	12.09.1997	12.03.2004
7	Nitazoxanide	Ms. Ind. Swift Ltd.	27.12.2002	17.03.2004
8	Trolamine	M/s. FDC Ltd.	01.03.1999	20.03.2004
9	Neotame	M/s. Nutra Sweet Co. (India)	04.01.2003	22.04.2004
10	Alfuzosin	M/s. Ranbaxy Labs. Ltd.	09.06.2003	14.05.2004
11	Tiagabine HCI	M/s. Sun Pharma	03.03.2003	14.05.2004

12	Ibandronic Acid	M/s. Roche Scientific Co. (India) Pvt. Ltd.	23.12.2003	18.05.2004
13	Memantine HCI	M/s. Sun pharma	25.06.2003	19.07.2004
14	Pimecrolimus	M/s. Novarits India ltd.	27.08.2002	23.07.2004
15	Rebamipide	M/s. Macleods Ltd.	22.04.2003	28.07.2004
16	Migilitol	M/s. Glenmark	27.06.2003	18.08.2004
17	Citicholine	M/s. Sun Pharma & M/s.Elder Pharma	Elder -23.12.1997 Sub - 02.12.2002	20.08.2004
18	Everolimus	M/s. Novartis India Ltd.	19.02.2004	30.08.2004
19	Voriconazole	M/s. Pharmacia	07.06.2004	09.09.2004
20	Orlistat	M/s Intas Pharma	10.10.2003	27.10.2004
21	Deflazacor	M/s. Macleods	28.10.2002	02.11.2004
22	Duloxetinet	M/s. Torrent Pharma	19.05.2003	02.11.2004
23	Atomoxetine	M/s. Torrent Pharma	23.08.2003	09.11.2004

ANNEXURE - II

NEW FIXED DOSE COMBINATIONS APPROVED DURING 2004

1	Nateglinide + Metformin
2	Desloratadine + Pseudoephedrine
3	Levocetirizine + Pseudoephedirne
4	S-Atenolol + Hyudrochlorthiazide
5	S-amlodipine + Atorvastatin
6	Amlodipine + Atorvastatin
7	Tamsulosin + Finasteride
8	S-amlodipine + Hydrochlorthiazide
9	Tiotropium + Formoterol Rotacaps/Inhaler
10	Lamivudine(ER) + Zidovudine(ER)+Nevirapine(ER)
11	Gatifloxacin +Dexamethasone Phos. Eye Drops
12	Esomeprazole + Domperidone SR
13	Aceclofenac + Paracetamol
14	Rabeprazole + Mosapride SR
15	Atorvastatin + Ezetimibe
16	Buprenorphine + Naloxone
17	Sucralfate + metronidozole + Lignocain Cream
18	Glibenclamide + Metformin SR
19	Escitalopram + Clonazepam
20	Dorzolamide + Timolol Eye Drops
21	Nebivolol + S(-) Amlodipine
22	Valdecoxib + Paracetomol
23	Amlodipine + Ramipril
24	Rebeprazole + Domperidone SR